June 22, 2026

Nexus Spine
% Jen McBride
Regulatory Affairs Consultant
MRC Global
9160 Hwy. 64 Suite 12
P.O. Box 330
Lakeland, Tennessee 38002

Re: K261279
Trade/Device Name: DeltaNEC Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: April 17, 2026
Received: April 17, 2026

Dear Ms. McBride:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

BRENT SHOWALTER -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261279

Please provide the device trade name(s).

DeltaNEC Interbody System

Please provide your Indications for Use below.

The Nexus Spine DeltaNEC Interbody System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc disease (DDD) at one or two contiguous levels from C2-T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The system is designed to be used with autogenous or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. The system is to be used in patients who have had six weeks of non-operative treatment. The system is intended to be used with the bone screw fixation provided and requires no additional fixation.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

DeltaNEC Interbody System
April 17, 2026

Company: Nexus Spine, LLC
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Salt Lake City, UT 84121

Primary Contact: Jen McBride
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Company/Secondary Contact: Jared Crocker
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Nexus Spine, LLC
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Trade Name: DeltaNEC Interbody System

Common Name: Intervertebral fusion device with integrated fixation, cervical

Classification: Class II

Regulation: 21 CFR 888.3080

Panel: Orthopedic

Product Code: OVE

Primary Predicate: Nexus Spine, LLC Stable-C Interbody System – K241467

Device Description:

The DeltaNEC Interbody System is an anterior cervical interbody device comprised of an interbody cage made from titanium alloy (Ti-6Al-4V) per ASTM F3001 and two fixation screws made from titanium alloy (Ti-6-Al-4V ELI) per ASTM F136. The device is offered in a variety of sizes to accommodate patient anatomy.

Indications for Use:

The Nexus Spine DeltaNEC Interbody System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc disease (DDD) at one or two contiguous

levels from C2-T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The system is designed to be used with autogenous or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. The system is to be used in patients who have had six weeks of non-operative treatment. The system is intended to be used with the bone screw fixation provided and requires no additional fixation.

Substantial Equivalence:

The subject Nexus Spine DeltaNEC Interbody System is substantially equivalent to the following legally marketed predicate devices:

Primary Predicate:

Nexus Spine, LLC, Stable-C Interbody System – K241467

Additional Predicate:

Aesculap Arcadius XP C – K153629

Nexus Spine, LLC, Preview III Anterior Cervical Plate – K223627

The subject components are similar in indications to the primary predicate Stable-C Interbody System (K241467) as well as the ArcadiusXP C device (K153629). Device sizing, geometry, and technological characteristics are similar to the predicates Stable-C (K241467) and Arcadius XP C (K153629). The subject screws are identical to those cleared for use with the Preview III plate in K223627. Materials, manufacturing, sterilization, and packaging are identical to those of the primary predicate, Stable-C (K241467).

Performance Testing:

The following performance testing has been conducted on the subject DeltaNEC implants: Static and Dynamic Compression per ASTM F2077-22, Static and Dynamic Compression-Shear per ASTM F2077-22, Static and Dynamic Torsion per ASTM F2077-22. Performance testing results show that the DeltaNEC Interbody system's mechanical strength properties met the established acceptance criteria and are substantially equivalent to those of predicate systems, which have established safety and efficacy.

Conclusion:

Based on the performance analysis and the comparison to the predicate device, the subject device is determined to be substantially equivalent to the predicate device.